AD________________

Award Number: W81XWH-04-1-0078

TITLE: Periscopic Spine Surgery

PRINCIPAL INVESTIGATOR: Kevin R. Cleary, Ph.D.

CONTRACTING ORGANIZATION: Georgetown University
Washington, DC 20007-2197

REPORT DATE: January 2005

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)

2. REPORT DATE
January 2005

3. REPORT TYPE AND DATES COVERED
Annual (22 Dec 2003 - 21 Dec 2004)

4. TITLE AND SUBTITLE
Periscopic Spine Surgery

5. FUNDING NUMBERS
W81XWH-04-1-0078

6. AUTHOR(S)
Kevin R. Cleary, Ph.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Georgetown University
Washington, DC 20007-2197

E-Mail: cleary@georgetown.edu

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)
The modern operating room requires an increasing number of new surgical instruments, monitoring and imaging devices, information systems, and communication networks. While these individual technologies are improving, attention must also be paid to integrating all of these resources so as to improve the quality and efficiency of surgical procedures. The OR2020 Workshop was organized by the ISIS Center at Georgetown University to identity the clinical and technical requirements for integrating advanced computer-assisted and robotic technologies into the next generation operating rooms and interventional suites. Five broad areas of technology requirements were identified:

1. Standards for devices and their use in the operating room (OR) are sorely needed. Every aspect of OR activity today is affected by their absence.
2. Interoperability of devices is essential for improved care and throughput. A "plug and play" medial network is needed.
3. Surgical robotics continues to develop and will play a role. Improvements in surgical robotics that build on their unique capabilities are needed.
4. Surgery-specific image acquisition, processing, and display are needed. The two-dimensional (2D) static images typically used today are not sufficient.
5. Communications issues must be addressed and aim toward attaining a common language, training requirements, and protocols to enable telecollaboration.

14. SUBJECT TERMS
Operating room, interventional suite, standards, robotics, telecollaboration

15. NUMBER OF PAGES
15

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

Table of Contents

I. INTRODUCTION

The modern operating room requires an increasing number of new surgical instruments, monitoring and imaging devices, information systems, and communication networks. While these individual technologies are improving, attention must also be paid to integrating all of these resources so as to improve the quality and efficiency of surgical procedures. The OR2020 Workshop was organized by the ISIS Center at Georgetown University to identify the clinical and technical requirements for integrating advanced computer-assisted and robotic technologies into the next generation operating rooms and interventional suites. The Workshop built on previous symposia, including the Operating Room of the Future (ORF) workshop sponsored by TATRC in 2002.

Approximately 100 participants, including physicians, engineers, and scientists, met for two days in March 2004. The Workshop consisted of plenary sessions, a keynote speaker, and two breakout sessions which were divided by Working Groups. The six Working Groups represented key areas of research and development:

1. Operational Efficiency and Workflow
2. Systems Integration and Technical Standards
3. Telecollaboration
4. Surgical Robotics
5. Intraoperative Diagnosis and Imaging
6. Surgical Informatics

From the Working Groups, five broad areas of technology requirements were identified:

1. **Standards** for devices and their use in the operating room (OR) are sorely needed. Every aspect of OR activity today is affected by their absence. This was a concern repeated often throughout the workshop. The OR team of the future must also be interdisciplinary, a theme noted by other related initiatives, including the NIH Roadmap and its Research Teams of the Future theme.

2. **Interoperability of devices** is essential for improved care and throughput. Currently, most devices and computer systems function as stand-alone islands of information. A "plug and play" medical network is needed.

3. **Surgical robotics** continues to develop and will play a role in the Operating Room of the Future. Improvements in surgical robotics that build on their unique capabilities are needed.

4. **Surgery-specific image acquisition, processing, and display** are needed. The two-dimensional (2D) static images typically used today are not sufficient. Image processing and visualization tools must be made available to the operating room.

5. **Communications issues** must be addressed and aim toward attaining a common language, training requirements, and protocols. This goal also depends upon development of network standards to enable telecollaboration.

A 74-page report was completed and copies have been sent to the sponsoring organizations. Much of the material can also be found on the web at or2020.org. The first chapter of the report is included in the next section.

II. BODY

CHAPTER 1: WORKSHOP OVERVIEW

1.1 INTRODUCTION

The "OR 2020 Workshop: Operating Room of the Future" was held on March 18-20, 2004, at Turf Valley Conference Center in Ellicott City near Baltimore, Maryland. The general objective of the workshop was to identify the clinical and technical requirements for deploying advanced computer-assisted and robotic technologies and biomedical modeling in next generation operating rooms and interventional suites. Integrated systems and the general character of the Operating Room of the Future (ORF) were defined, with the year 2020 used as a target timeframe. The workshop consisted of a series of plenary sessions and breakout meetings of the six Working Groups. Approx-imately 75 invited experts, both PhDs and MDs, participated. (See Figure 1 on the next page for a group photograph.)

The OR 2020 workshop was organized by the Imaging Science and Information Systems (ISIS) Center, Department of Radiology, of the Georgetown University Medical Center, Washington, DC; the Innovative Surgery Committee at the Walter Reed Army Medical Center, Washington, DC; and the Telemedicine and Advanced Technology Research Center (TATRC) at Fort Detrick, Maryland. The workshop was supported by the U.S. Army Medical Research and Materiel Command, the National Science Foundation, and the National Institute of Biomedical Imaging and Bioengineering at the National Institutes of Health. Corporate sponsors were GE Medical Systems, Karl Storz Endoscopy, MedStar Health/ Georgetown University Hospital, Olympus Surgical Division, Siemens Corporate Research, and Stryker Endoscopy.

This chapter begins by summarizing the common themes and recommendations from the workshop. Next, the focuses of the six Working Groups are presented in brief, followed by a snapshot of the workshop's rationale, planning process, and execution. Summaries of participants' views on needs and expected changes in the ORF are then presented, based on responses to a pre-workshop questionnaire that was sent to all participants.

This report can also be found on the World Wide Web, by starting at
http://www.caimr.georgetown.edu
and following the links to the workshops and the OR2020 workshop.

At the time this report was printed, we were also maintaining the conference web site at
http://www.or2020.org/
and additional workshop materials such as some of the presentations can be found there.

Figure 1: Photograph of participants

1.2 COMMON THEMES AND RECOMMENDATIONS

There were a number of common themes that were identified during the workshop and they are noted as follows. The five common themes that were identified are:

1. **Standards** for devices and their use in the operating room (OR) are sorely needed. Every aspect of OR activity today is affected by their absence, from nonstandardized and incomplete patient records, to varied and unstandardized imaging formats of visual information that is needed during surgeries, to varied and sometimes imprecise language used in communicating among surgical team members.

2. **Interoperability of devices** is needed for development of a smoothly operating OR as well as for improved surgeries. Currently, most devices and computer systems function as stand-alone islands of information and their use requires a great deal of surgeons' time and effort.

3. **Surgical robotics** continues to develop and its role in the Operating Room of the Future is still being defined. Improvements in surgical robotics are needed to build on their unique capabilities such as precision, accuracy, ability to withstand ionizing radiation, and dexterity in small spaces inside of the human body.

4. **Improved, surgery-specific image processing and display** are needed for effective use in the OR. The two-dimensional (2D) static images that are typically available in today's OR do not accommodate the 3D and real-time imaging needs of surgeons in most specialty disciplines.

5. **Communications issues** must be addressed and aim toward attaining a common language, training requirements, and protocols for effectively performing advanced surgeries and using telecommunications-ready tools as needed.

The following recommendations were made, based on these five themes:

1. Standards, standards, standards. If there was an overarching theme of the workshop, this was it. Standards are needed in all areas, and must be developed through a concerted effort involving companies, government agencies, academic institutions, and perhaps standards organizations. Research studies of surgical workflow and efficiencies are required to develop practice standardization and thus realize improvements.

2. Progress on the first recommendation will also enable progress on device interoperability. It is recommended that research be devoted to developing common user interfaces among medical devices, and that the device industry take the lead in performing this research with input for academic institutions and government agencies. A "plug and play" architecture for medical devices is also needed.

3. Research in surgical robotics should focus both on improving the capabilities of these systems and integrating them with the surgical workflow. These systems could ultimately help improve patient safety by incorporating built-in safety checks and integrating them both with imaging and the electronic patient record.

4. Attaining advanced and improved surgery-specific image processing and display systems requires engineers and designers to work with surgeons to identify the needs and risks in using these systems. Readily available and flexible, real-time 3D imaging systems that use one standard platform for all imaging modalities are needed in current and future ORs. It is recommended that manufacturers and the device industry as a whole be encouraged to build imaging products that enable surgery-specific work.

5. A well-developed, dedicated medical network is needed to enable routine telecollaboration. An industry-grounded meeting to be attended by government stakeholders (including lawmakers), industry developers, telecommunications industry personnel, and surgical personnel should be arranged to address the needs of telecollaboration in medicine and surgery.

1.3 WORKING GROUPS

The OR2020 workshop consisted of plenary sessions and Working Group meetings during an intensive two-day period. The Working Groups each were charged with investigating a specific clinical and technical area related to the ORF. The six Working Groups were as follows. Group 1: Operational Efficiency and Workflow; Group 2: Systems Integration and Technical Standards; Group 3: Telecollaboration; Group 4: Surgical Robotics; Group 5: Intraoperative Diagnosis and Imaging; Group 6: Surgical Informatics. A brief summary of each group's work is as follows:

Working Group 1: **Operational Efficiency and Workflow.** This group focused on examining requirements for achieving increased efficiencies in the OR. These requirements focused on needed mechanisms for accessing and obtaining correct and current patient-related information and scheduling, and accessing use of correct surgical tools. The group also discussed developing surgical practice standards that define day-to-day, step-by-step surgical workflows.

Working Group 2: **Systems Integration and Technical Standards.** This group focused on the need for interoperability among a broad range of devices that are used in the OR. To achieve seamless integration among devices, a standard interface for interoperability among these technologies could be developed using a plug and play platform. This group also discussed the need for device standards that will enable configurability and easy use of these tools in the OR.

Working Group 3: **Telecollaboration.** This group focused on current and future uses of telecollaboration for purposes of remote consultation, mentoring, monitoring, robot manipulation, and other functions. An absence of standards in every facet of this form of telecommunications-assisted delivery was noted by this group. Standards are needed in areas related to clinical uses of telecollaboration (such as training). Other needed standards are related to technical requirements of telecollaboration (e.g., for a low latency data compression algorithm that will enable low bandwidth synchronized transmission of data to the OR). Finally, this group identified significant regulatory and legal hurdles that are slowing adoption of telecollaboration in the OR.

Working Group 4: **Surgical Robotics.** This group discussed the many clinical benefits of using robotic systems, particularly those that complement and extend human capabilities in the OR. Meeting technical needs for improving surgical robotics use requires building on robots' unique capabilities, such as their advanced precision, accuracy, strength, and dexterity. This group also discussed the importance of risk and safety issues pertaining to the use of robots in the OR.

Working Group 5: Intraoperative Imaging. This group focused on a central issue in intraoperative imaging today: namely, the difficulty for surgeons to obtain information from imaging devices in the OR. The need to present images in interactive and 3D imaging modalities, and for developing the capabilities to integrate and manipulate these data, were discussed.

Working Group 6: **Surgical Informatics.** This group focused on defining the nascent discipline of surgical informatics and identifying certain limitations that are impeding its development. The group noted a particular need for informatics systems that integrate preoperative, operative, and postoperative information and make it available where and when needed. In addition, a set of unified standards for procedures and use of surgical informatics must be defined and implemented, this Working Group concluded.

1.4 WORKSHOP RATIONALE, PLANNING PROCESS, AND EXECUTION

1.4.1 Rationale

A number of meetings that focused on needs in the ORF have been held in recent years. The OR2020 Workshop was committed to addressing issues that have consistently arisen at these meetings and elsewhere in discussion about the ORF. These issues include the need for widely adopted standards, concerns about ensuring patient safety, and the uncoordinated use of technology in the OR. Identifying mechanisms to address these issues and posing recommended solutions was the rationale for holding this workshop and inviting both clinical and technical experts to participate and share their views.

1.4.2 Planning Process

Planning for the OR2020 Workshop began in the Fall of 2002, when the ISIS Center at Georgetown University Medical Center began to formulate a broader direction for studying the ORF and its needs and purposes. It was felt that organizing a workshop was a good way to obtain a better understanding of this field of growing interest and concern. Collaboration with the Walter Reed Innovative Surgery Committee and TATRC was initiated. Funding was solicited from various agencies, and preparations were begun in earnest in the Summer of 2003. The organizing committee met several times during the Fall of 2003 to create the final program and identify participants. Invitations were sent in late 2003, followed by a pre-Workshop questionnaire. The Workshop was held March 18-20, 2004.

1.4.3 Execution

The Workshop consisted of plenary sessions and Working Group meetings. The plenary sessions were aimed at providing background for both clinical and technical areas. The Working Groups focused on specific areas of concern in the ORF, such as intra-operability of devices, telecollaboration needs, and surgical robotics. Each Working Group had a technical leader (PhD) and a clinical leader (MD).

The OR2020 workshop began with a reception on the evening of Thursday, March 18, followed by an organizing committee and Working Group leaders' meeting. The opening session was held the next morning and included clinical and technical overviews on the evolution of surgery, a view of a testbed ORF at the Massachusetts General Hospital, and a panel discussion of surgical specialties and practitioners' needs in the ORF. These clinical plenary sessions were followed by technical presentations on topics such as device independence in the OR, the state-of-the-art in robotics, image-guided therapy, and surgery-specific workflow. Additional plenary sessions followed after a break, and included topics such as interventional oncology and the future of imaging. Meetings of the six Working Groups were interspersed throughout the workshop days, with time also allocated for summary presentations following most of the Working Group meetings.

There were two extended breakout sessions for Working Group meetings. Each Working Group was assigned a specific task, as follows:

Breakout Session 1: Current status and clinical requirements
Task 1: Review contemporary issues in each Working Group's area in today's OR.
Task 2: Define the clinical needs for contemporary and future ORs.

Breakout Session 2: Technical requirements and research priority formulation
Task 1: Based on clinical needs, define the technical requirements.
Task 2: Summary. Prepare a list of research priorities and recommendations.

Working Group status reports were presented twice during the Workshop, in 10-minute sessions to the entire conference audience following the first and second Breakout Sessions.

To move forward quickly during the Workshop, a great deal of preparation was done prior to the Workshop. In particular, a pre-Workshop questionnaire was sent to all of the participants which asked them to identify research issues and suggest relevant references. The questionnaire served to get all of the participants thinking about the field and provided excellent background for the Workshop process. General questions included:

1. What are the main technical problems and research needs for the ORF?
2. What are the major infrastructure and administrative issues that must be addressed to develop the integrated ORF?

As part of the questionnaire, participants were asked to recommend three papers that were relevant to the field and a bibliography was generated which is presented in Appendix C. Most of the participants responded and the responses were used to help generate a 31-page pre-Workshop report.

This report provided general background for each Working Group, summarized the questionnaire responses, and included a bibliography. All of this effort served to acclimatize the participants beforehand so that informed discussion could move ahead quickly at the Workshop. The questionnaire itself and all of the responses are available on the Workshop's web site, as noted at the end of section 1.1.

1.5 PRE-WORKSHOP QUESTIONNAIRE

As noted, a pre-Workshop questionnaire was sent to all attendees, and in addition to several general questions, the questionnaire contained three specific questions for each Working Group:

1. What are the major technical problems relevant to your Working Group?
2. What other factors are relevant for your Working Group?
3. What procedures could benefit most from advances in this area?

The responses to the specific questions from the Working Groups are briefly summarized here. Participants were encouraged to look at all the responses, and these were made available prior to the workshop.

1.5.1 Working Group 1. Operational Efficiency and Workflow

Summary of responses

1.5.1.1 Major Technical Problems. From the questionnaire responses, participants agreed that information flow is a critical concept. One participant suggested that there is a lack of information technology for the OR; and another participant described this as a lack of situational awareness. Another participant suggested that automation (such as use of radio frequency identification devices, or RFID) could reduce time and errors while improving efficiency. Finally, it was suggested that there is a lack of real-time information regarding upstream and downstream processes, which makes the system slow to respond to variances that occur in the OR (and there can be a lot of variances).

1.5.1.2 Other Factors. Several other factors were identified as important for operational efficiency and workflow. The need for more training of staff was emphasized. The culture of the OR and its slow acceptance of new technology were listed as barriers. The myriad of paper records is a problem. Management of unplanned events (which is a regular occurrence) is difficult. In addition, one respondent noted that small increments of saved time that do not result in improved throughput (more cases or reduced overtime) are of limited utility.

1.5.1.3 Procedures. In attempting to identify procedures that could benefit most from improvements in operational efficiency and workflow, most respondents noted that all procedures could benefit. One respondent noted that these improvements were particularly suited to surgeons who do 60-to-80-minute procedures that have limited variability. Another respondent noted that an additional benefit could be improved patient safety.

1.5.2 Working Group 2. Systems Integration and Technical Standards

Summary of responses

1.5.2.1 Major Technical Problems. The major technical problem related to systems integration and technical standards is the lack of an accepted standard for device integration. The development of such a standard is no doubt a large undertaking, and one respondent suggested that what is needed is a clear understanding of surgical workflow and modeling tools. Another respondent noted that it is difficult to provide open systems while ensuring safety, security, and patient confidentiality. One more respondent stated that integrated control and communication systems require that manufacturers must be motivated by economic drivers, and must feel secure from experiencing legal and FDA repercussions. Finally, one respondent stated that there are no major technical problems and that the manufacturing sector has automated factory workflow for years with proprietary and nonproprietary systems.

1.5.2.2 Other Factors. There were a number of other factors listed by the questionnaire respondents. The proprietary interests of manufacturers were listed several times. One respondent stated that the manufacturers fear providing opportunities for competition. Another respondent noted that no large institution is pushing for standardization and that the regulatory environment discourages integration since the FDA clears devices only for specific "indications for use." Finally, one respondent stated that there is a lack of understanding (either too simplistic or overly complicated) of how systems integrate and of the issues that impinge on integration.

1.5.2.3 Procedures. In regard to defining procedures that can benefit most from advances in systems integration and technical standards, one respondent suggested that all OR procedures would benefit. Other respondents noted that minimally invasive procedures and image-guided procedures could benefit.

1.5.3 Working Group 3. Telecollaboration

Summary of responses

1.5.3.1 Major Technical Problems. While there were many responses to this question, most of the responses did not actually list technical problems. Instead, respondents identified related issues such as the cost of equipment and infrastructure and the lack of adequate support staff. It was noted that there was a lack of clinical trials that demonstrate the value of telecollaboration.

1.5.3.2 Other Factors. Several other factors were mentioned as limiting the use of telecollaboration. The major other factor listed was medical liability, including licensure and credentialing. In addition, there is no practical system for financial compensation of telementoring or for accommodation of time-zone differences. The lack of acceptance by third-party payers and state licensing agencies was also listed, as was the difficulty of scheduling collaborating physicians.

1.5.3.3 Procedures. A number of different procedures were listed that could benefit most from advances in telecollaboration. One respondent felt that every surgeon performing basic procedures in community practice could benefit from the mentoring delivered by an expert observer. Similarly, for advanced procedures, expert physicians would like the support of national and international experts. Another respondent suggested that among the best applications of telecollaboration would be demonstrating/observing the first few of any procedures that were unfamiliar to a physician. Still another respondent listed image-guided therapies, laparoscopic, and robotic-aided surgeries as particularly appropriate for telecollaboration.

Also mentioned were time-sensitive procedures such as emergency trauma interventions and cardiac surgeries. One respondent listed as appropriate those procedures that are seldom performed by most practitioners – that is, those that are rare or those that are just becoming established routines. The same respondent also listed interventional procedures that require collaboration across disciplines such as cardio or vascular procedures.

1.5.4 Working Group 4. Surgical Robotics

Summary of responses

1.5.4.1 Major Technical Problems. Many technical problems were listed by the respondents. It was noted that current surgical robots are too big and too expensive. The lack of haptics was noted by one respondent. Another comment was that there are not too many operations that actually benefit from robotics and it can actually be a productivity disabler. One respondent suggested that the equipment's fault tolerance needs to be improved. Another stated that robots are difficult to use and generally require more set-up time, especially when registration and/or fixation is required. Finally, one person suggested that robotics are not being adapted to the surgeon's working requirements and the patient's bodily needs.

In terms of technical problems related to surgical instrumentation, one respondent noted that voice recognition is still not where it needs to be for real-world use. Another respondent listed the problems with minimally invasive surgery, including placement and navigation of the instruments. Respondents also listed the needs for both multimodality on-line instrument control and for an integrated view of all relevant navigation and physiological data.

1.5.4.2 Other Factors. Cost was the other major factor mentioned by respondents as limiting the use of robotics. Other issues included training, the large size of the instrument, and the lack of a demonstrated benefit for mainstream use of surgical robots.

1.5.4.3 Procedures. Several different procedures were mentioned that could benefit from advances in robotics. One respondent stated that any minimally invasive procedure that is currently expensive to do (in terms of equipment or OR time) and is very demanding could benefit. Another respondent felt that it would be most beneficial for procedures, such as neurosurgery and heart surgery, that have a "scaling barrier". Lengthy procedures or procedures that demand prolonged or exact motor control were also mentioned as possibly benefiting from advances in robotics as was any procedure requiring complex reconstruction. Bone-oriented procedures were also mentioned.

1.5.5 Working Group 5. Intraoperative Diagnosis and Imaging

Summary of responses

1.5.5.1 Major Technical Problems. A number of different technical problems were listed by the respondents. It was noted that high quality imaging devices such as CT and MRI are generally too large for the OR's physical environment. Radiation exposure is an issue for x-ray imaging, which is otherwise one of the more practical OR imaging modalities. Other respondents noted that devices designed for the OR have poor image quality, the information is still presented mostly 2D (no real-time 3D is available), and the information is anatomical only (i.e., it is non-functional).

Another respondent noted the lack of integration of molecular imaging methods into intraoperative diagnosis. There is a need for better molecular tracers, both in marker intensity and specificity. One respondent listed the issues as biochemical sensitivity, spatial resolution, knowing what tracers are appropriate for a particular clinical task, equipment size, and other special environmental needs.

More than one respondent stated that modeling is an issue. There is a lack of adequate models for virtual representations of internal organs. There is a need for real-time computation for deformable registration and reconstruction and updating of image models.

Finally, it was noted that there is a need for more reliable and less expensive tracking devices. There are a lack of adequate software tools to conduct reliable intraoperative analysis, and an absence of consolidation of all of the intraoperative information into a comprehensive format.

1.5.5.2 Other Factors. There were several other factors mentioned as limiting the use of intraoperative diagnosis and imaging. These factors relate to how to best integrate the equipment into the OR and the surgical workflow. Other key factors concern questions of cost, reimbursement, and equipment ownership. One respondent noted that the equipment was disruptive to the flow of surgery. It is cumbersome, inconvenient, and requires collaboration with other departments to insure the availability of a technologist in the OR without whom the surgeon cannot operate. Another respondent listed other factors including sterile field violation, applications not designed for surgical OR interactions, and applications placed in geographically undesirable locations in the OR.

1.5.5.3 Procedures. A wide array of procedures were mentioned that could benefit from advances in intraoperative diagnosis and imaging. One respondent stated that most procedures were amenable to these advances but, in particular, the resection and therapy of malignant tumors would benefit most because use of this technology would allow the surgeon to remove all malignant tissue and reduce the damage to the neighboring anatomy. Another respondent similarly commented that all operations involving potential for vascular compromise of tissues were candidates, such as resection of brain tumors and metastases, resection of breast cancer, and auxiliary node sampling.

Other procedures that would benefit from advances included: prostate brachytherapy and surgery; cardiac interventions, neurosurgery, liver surgery, lung surgery, cancer surgeries, and orthopedics. The biggest growth is believed to be in soft-tissue MIS procedures. In the specific case of x-ray CT, probably some of the more immediate applications to benefit from advances are spinal, skull-base, and sinus procedures.

1.5.6 **Working Group 6. Surgical Informatics**

Summary of responses

1.5.6.1 Major Technical Problems. From the questionnaire responses, the major technical problem seems to be that surgical informatics is still evolving as a discipline. High quality surgical informatics systems do not seem to be available yet and there is no ontology or standard for their development. It is difficult to integrate the different types of information needed in surgical decision making into a coherent presentation and there is a need for decision support methods to integrate this information. There are no reliable content-based search techniques available and high performance computing has not been advantageously used.

In the area of surgical atlases, major technical problems include building quality anatomical atlases for organs other than the brain (where some preliminary solutions exist) and building patient-specific biomedical and simulation models. One respondent also noted that the bioinformatics field has provided many useful tools for this type of work, but it should be expanded to fully include images, techniques, and situational searches. By "situational searches," the respondent is referring to something like an intelligent agent that could examine the ongoing surgical operation and provide suggestions.

1.5.6.2 Other Factors. Several others factors were mentioned by the respondents as limiting the use of surgical informatics. In particular, it was noted that there was a lack of validation studies to convince the leaders in surgery of the value of surgical informatics. It was also noted that adopting use of surgical informatics in the OR will require a total change of the intra-operative procedure, a different workflow, and most of all, additional cost in time of the surgery.

Other factors limiting the use of surgical informatics that were listed by respondents included the need for a research OR that is charged with investigating the problems to be solved and the need to find surgeons who are willing to be involved in the development of these systems. The problems of cost and nursing turnover were also mentioned, along with the lack of inter-institution data accessibility and related regulations.

1.5.6.3 Procedures. Several different types of procedures were mentioned that could benefit from advances in surgical informatics. In particular, procedures with difficult or unusual complications, complex procedures that could benefit from extensive pre-planning, and any procedure with a long patient history were mentioned. One respondent listed the categories of intraoperative pathology, telementoring, telesurgery, and virtual reality applications including training and mission rehearsal.

Additional procedures suggested were orthopedics applications in which mechanical models were important, and neurosurgical procedures for which atlases would be beneficial. Another respondent listed tumor resection in critical organs and lymph node biopsies and resections. Finally, other suggestions included 1) bone procedures; 2) trauma care; and 3) vascular interventions, neural interventions, and tumor ablations.

III. KEY RESEARCH ACCOMPLISHMENTS

The workshop successfully accomplished the following:

- Brought together over 100 participants from clinical, technical, scientific, and related areas to discuss the future of the operating room.
- Made recommendations for research priorities overall and within the six working groups.
- Produced a hard copy report, DVD, and a web site

IV. REPORTABLE OUTCOMES

Reportable outcomes from the workshop are:

- Hard copy 74-page report
- DVD with reports, audio, and transcripts.
- Web site or2020.org

V. CONCLUSIONS

MRMC/TATRC support for this workshop was instrumental in enabling a high quality meeting and final report. There were many participants from TATRC and Walter Reed ensuring that military needs and issues were raised and considered. The workshop produced a 74-page final report and summary DVD that will lay the groundwork for research priorities for the Operating Room of the Future. Further information is available by contacting the principal investigator, Kevin Cleary, PhD, at 202-687-8253 or by email at cleary@georgetown.edu.

VI. REFERENCES

The hard copy of the workshop includes a 6-page list of recommended references and reading.

VII. APPENDICES

Hard copies and DVDs of the workshop materials will be made available to MRMC. These materials can also be requested by emailing the principal investigator, Kevin Cleary, PhD, at cleary@georgetown.edu.